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From: Ronald I. Eisenstein Leena H. Karttunen	Date: September 19, 2006	No. of Pages: 16 (including this page)	700953-53666
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Practitioner's Docket No. 700953-53666**PATENT****IN THE UNITED STATES RECEIVING OFFICE**

International Application Number	International Filing Date	International Earliest Priority Date
PCT/US2004/037810	12 November 2004 (12.11.2004)	12 November 2003 (12.11.2003)

U.S. SERIAL NO.: 10/579,007

TITLE OF INVENTION: SYSTEM FOR TREATING AND PREVENTING BREAST CANCER

APPLICANT(S) FOR DO/EO/US: Panicali et al.

Mail Stop PCT (U.S. Receiving Office)
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the following papers are being facsimile transmitted to the United States Patent and Trademark Office at (703) 305-3230 on the date shown below:

1. Facsimile Cover Sheet (1 pg.);
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CONFIRMATION: DATE SENT _____ TIME _____ BY _____

INTEROFFICE TO: o Albany o Boston o Buffalo o Garden City o Hartford o Manchester o New York City
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From: Ronald I. Eisenstein Leena H. Karttunen	Date: September 19, 2006	No. of Pages: 16 (including this page)	Client/Matter: 700953-53666
User #: 7468	Ext: 6054	Disbursement Amount: \$	

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SignatureMegan L. Stenbridge

Typed or printed name of person signing Certificate

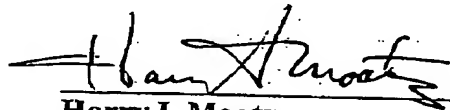
**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
UNITED STATES PATENT AND TRADEMARK OFFICE**

LIMITED RECOGNITION UNDER 37 CFR § 11.9(b)

Leena H. Karttunen is hereby given limited recognition under 37 CFR §11.9(b) as an employee of Nixon Peabody LLP, to prepare and prosecute patent applications wherein the patent applicant is the client of Nixon Peabody LLP and an attorney or agent of record in the applications is a registered practitioner who is a member of Nixon Peabody LLP. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Leena H. Karttunen ceases to lawfully reside in the United States, (ii) Leena H. Karttunen's employment with Nixon Peabody LLP ceases or is terminated, or (iii) Leena H. Karttunen ceases to remain or reside in the United States on an H-1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

Limited Recognition No. L0207
Expires: February 11, 2007



Harry I. Moatz
Director of Enrollment and Discipline

FORM PTO-1390 (REV 12-2001)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEYS DOCKET NUMBER 700953-53666
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/579,007
INTERNATIONAL APPLICATION NO. PCT/US2004/037810	INTERNATIONAL FILING DATE 12 November 2004	PRIORITY DATE CLAIMED 12 November 2003	
TITLE OF INVENTION SYSTEM FOR TREATING AND PREVENTING BREAST CANCER			
APPLICANT(S) FOR DO/EO/US Panicali et al.			
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. <input type="checkbox"/> This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> has been communicated by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <input type="checkbox"/> is attached hereto. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). <ol style="list-style-type: none"> <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> have been communicated by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input type="checkbox"/> have not been made and will not be made. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11 to 20 below concern document(s) or information included:</p> <ol style="list-style-type: none"> <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. <input type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. <input type="checkbox"/> A substitute specification. <input checked="" type="checkbox"/> A change of power of attorney and/or address letter. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). <input checked="" type="checkbox"/> Other items or information: Certificate of Facsimile Transmission, Certificate of Limited Recognition (L. H. Karttunen). 			

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.50)		INTERNATIONAL APPLICATION NO.		ATTORNEYS DOCKET NUMBER	
10/579,007		PCT/US2004/037810		700953-53666	
The following fees are submitted:				CALCULATIONS	PTO USE ONLY
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)).....				\$	
22. <input type="checkbox"/> Examination fee.....				\$	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....					
All other situations.....					
23. <input type="checkbox"/> Search fee.....				\$	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....					
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....					
All other situations.....					
TOTAL OF 21, 22 and 23 =				\$	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(e) or (e) or computer program listing filed in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250.00	\$	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		x \$50.00	\$	
Independent claims	- 3 =		x \$200.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360.00	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
SUBTOTAL =				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
TOTAL FEES ENCLOSED =				\$ 0.00	
				Amount to be refunded:	\$
				Amount to be charged:	\$

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. 19-2380 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-2380. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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Boston, MA 02110-2131



SIGNATURE

Ronald I. Eisenstein / Leena H. Karttunen

30,628 / L0207

REGISTRATION NUMBER

NIXON PEABODY LLP
100 Summer Street
Boston, Massachusetts 02110

Attorney's Docket No. 700953-53666

Page 1 of 5

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed at 201) below or an original, first and joint inventor (if plural names are listed at 201-208 below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SYSTEM FOR TREATING AND PREVENTING BREAST CANCER

which is described and claimed in:

- ☐ the specification attached hereto.
- ☐ the specification in U.S. Application Serial Number _____ filed on;
- ☒ the specification in PCT International Application Number PCT/US2004/037810 filed on November 12, 2004 and as amended in a preliminary amendment submitted on May 11, 2006 with the 371 National Stage Entry.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a). I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign/PCT Applications and Any Priority Claims Under 35 U.S.C. §119:			
Application No.	<u>Filing Date</u>	<u>Country</u>	<u>Priority Claimed under 35 U.S.C. §119?</u>
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose material information as defined in 37 CFR §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

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Boston, Massachusetts 02110

Attorney's Docket No. 700953-53666

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Prior U.S. Applications or PCT International Applications Designating the U.S.-Benefit under 35 U.S.C. §120					
U.S. Applications			Status (Check One)		
Application Serial No.	U.S. Filing Date	Patented	Pending	Abandoned	
PCT Applications Designating the U.S.					
Application No.	Filing Date	U.S. Serial No. Assigned			
PCT/US2004/037810	12 Nov 2004			X	

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(35 U.S.C. §119(e))

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

<u>Applicant</u>	<u>Provisional Application Number</u>	<u>Filing Date</u>
Dennis L. Panicali et al.	60/519,427	November 12, 2003

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) with full powers of association, substitution and revocation to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Ronald I. Eisenstein (Reg. No. 30,628)
 30,727)
 Leena Karttunen (L0207)
 32,163)
 Edwin V. Merkel (Reg. No. 40,087)
 58,109)

David S. Resnick (Reg. No. 34,235)
 Gunnar G. Leinberg (Reg. No. 35,584)
 J. Amelia Feulner (Reg. No. 58,039)

Michael L. Goldman (Reg. No.
 Joseph Noto (Reg. No.
 Candace Summerford (Reg. No.

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100 Summer Street
Boston, Massachusetts 02110

Attorney's Docket No. 700953-53666

Page 3 of 5

SEND CORRESPONDENCE TO: Ronald I. Eisenstein NIXON PEABODY LLP 100 Summer Street Boston, Massachusetts 02110	DIRECT TELEPHONE CALLS TO: Ronald I. Eisenstein (617) 345-6054
---	---

201	FULL NAME OF INVENTOR	LAST NAME PANICALI	FIRST NAME DENNIS	MIDDLE NAME L.
	RESIDENCE & CITIZENSHIP	CITY Acton	STATE OR FOREIGN COUNTRY MA	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 114 Nonset Path	CITY Acton	STATE OR COUNTRY AND ZIP CODE MA 01720

202	FULL NAME OF INVENTOR	LAST NAME MAZZARA	FIRST NAME GAIL	MIDDLE NAME P.
	RESIDENCE & CITIZENSHIP	CITY Winchester	STATE OR FOREIGN COUNTRY MA	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 22 Rangeley Road	CITY Winchester	STATE OR COUNTRY AND ZIP CODE MA 01890

203	FULL NAME OF INVENTOR	LAST NAME GRITZ	FIRST NAME LINDA	MIDDLE NAME R.
	RESIDENCE & CITIZENSHIP	CITY SOMERVILLE	STATE OR FOREIGN COUNTRY MA	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 3 Emerson Street	CITY Somerville	STATE OR COUNTRY AND ZIP CODE MA 02143

NIXON PEABODY LLP
100 Summer Street
Boston, Massachusetts 02110

Attorney's Docket No. 700953-53666

Page 4 of 5

204	FULL NAME OF INVENTOR	LAST NAME SCHLOM	FIRST NAME JEFFREY	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY Potomac	STATE OR FOREIGN COUNTRY MD	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 10301 Scerrel Avenue	CITY Potomac	STATE OR COUNTRY AND ZIP CODE MD 20854

205	FULL NAME OF INVENTOR	LAST NAME TSANG	FIRST NAME KWONG-YOK	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY Bethesda	STATE OR FOREIGN COUNTRY MD	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 5420 York Avenue	CITY Bethesda	STATE OR COUNTRY AND ZIP CODE MD 20814

206	FULL NAME OF INVENTOR	LAST NAME HODGE	FIRST NAME JAMES	MIDDLE NAME W.
	RESIDENCE & CITIZENSHIP	CITY Gaithersberg	STATE OR FOREIGN COUNTRY MD	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 19030 Montgomery Village Avenue	CITY Gaithersberg	STATE OR COUNTRY AND ZIP CODE MD 20879

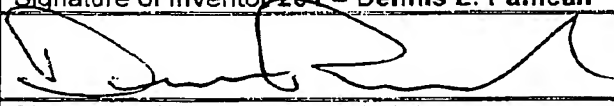
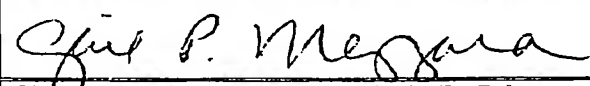
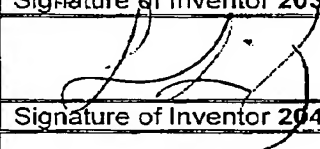
I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

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Boston, Massachusetts 02110

Attorney's Docket No. 700953-53666

Page 5 of 5

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature of Inventor 201 – Dennis L. Panicali	Date:
	5/22/06
Signature of Inventor 202 – Gail P. Mazzara	Date:
	5/22/06
Signature of Inventor 203 – Linda R. Gritz	Date:
	5/22/06
Signature of Inventor 204 – Jeffrey Schlom	Date:
Signature of Inventor 205 – Kwong-Yok Tsang	Date:
Signature of Inventor 206 – James W. Hodge	Date:

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Boston, Massachusetts 02110

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SYSTEM FOR TREATING AND PREVENTING BREAST CANCER

which is described and claimed in:

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- ☐ the specification in U.S. Application Serial Number _____ filed on;
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			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

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<u>U.S. Applications</u>		Status (Check One)			
Application Serial No.	U.S. Filing Date	Patented	Pending	Abandoned	
PCT Applications Designating the U.S.					
Application No.	Filing Date	U.S. Serial No. Assigned			
PCT/US2004/037810	12 Nov 2004			X	

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David S. Resnick (Reg. No. 34,235)
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Michael L. Goldman (Reg. No.
 Joseph Noto (Reg. No.
 Candace Summerford (Reg. No.

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	POST OFFICE ADDRESS	POST OFFICE ADDRESS 114 Nonset Path	CITY Acton	STATE OR COUNTRY AND ZIP CODE MA 01720

202	FULL NAME OF INVENTOR	LAST NAME MAZZARA	FIRST NAME GAIL	MIDDLE NAME P.
	RESIDENCE & CITIZENSHIP	CITY Winchester	STATE OR FOREIGN COUNTRY MA	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 22 Rangeley Road	CITY Winchester	STATE OR COUNTRY AND ZIP CODE MA 01890

203	FULL NAME OF INVENTOR	LAST NAME GRITZ	FIRST NAME LINDA	MIDDLE NAME R.
	RESIDENCE & CITIZENSHIP	CITY SOMERVILLE	STATE OR FOREIGN COUNTRY MA	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 3 Emerson Street	CITY Somerville	STATE OR COUNTRY AND ZIP CODE MA 02143

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	POST OFFICE ADDRESS	POST OFFICE ADDRESS 5420 York Avenue	CITY Bethesda	STATE OR COUNTRY AND ZIP CODE MD 20814

206	FULL NAME OF INVENTOR	LAST NAME HODGE	FIRST NAME JAMES	MIDDLE NAME W.
	RESIDENCE & CITIZENSHIP	CITY Gaithersburg	STATE OR FOREIGN COUNTRY MD	COUNTRY OF CITIZENSHIP US
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 19030 Montgomery Village Avenue	CITY Gaithersburg	STATE OR COUNTRY AND ZIP CODE MD 20879


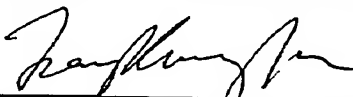
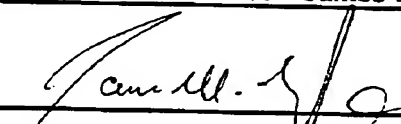
I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

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imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature of Inventor 201 – Dennis L. Panicali	Date:
Signature of Inventor 202 – Gail P. Mazzara	Date:
Signature of Inventor 203 – Linda R. Gritz	Date:
Signature of Inventor 204 – Jeffrey Schlom	Date:
	5-23-06
Signature of Inventor 205 – Kwong-Yok Tsang	Date:
	5-23-06
Signature of Inventor 206 – James W. Hodge	Date:
	5-23-06